

JAN 22 1997

K954717

APPENDIX E

510(k) Summary

510(k) Summary for the
SODEM HIGH SPEED SYSTEM
(Per 21 CFR 807.92)

1. APPLICANT

sodemsystems

Sodem Diffusion S.A.

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Date of Summary Preparation: October 11. 1995

2. DEVICE NAME

Trade Name: SODEM HIGH SPEED SYSTEM

Classification Name: Powered simple cranial drills, burrs, and accessories
Pneumatic cranial drill motors for neurosurgery
Blades, saw, surgical cardiovascular
Pneumatically powered saw

Common/Usual Name: Surgical power system

3. PREDICATE DEVICES

The SODEM HIGH SPEED SYSTEM claims equivalence to the following systems:

- Zeppelin M.D.S. (K922299)
- Zimmer Ultra Power System (No K Number Identified)
- Anspach System 65K (K831756)
- Midas Rex System (No K Number Identified)

4. **DEVICE DESCRIPTION**

The SODEM HIGH SPEED SYSTEM is a modular, pneumatic, high speed instrument system consisting of a handpiece and accessories/attachments (including but not limited to adapter, spindles, and burrs).

5. **INTENDED USE**

The SODEM HIGH SPEED SYSTEM (with associated accessories/attachments) is intended for use for neurosurgery (spine and craniotomy) and median sternotomy.

6. **BASIS FOR CLAIM OF SUBSTANTIAL EQUIVALENCE**

sodemsystems claims substantial equivalence to other pneumatic high speed surgical instruments, specifically the Zeppelin M.D.S System, Zimmer Ultra Power System, Midas Rex System, the Anspach 65K System. This claim is based on equivalence in:

Intended Use: The intended use of the SODEM HIGH SPEED SYSTEM (with associated accessories/attachments) is identical to that of the cited predicate systems as cited above.

Materials: The materials of the SODEM HIGH SPEED SYSTEM which are in direct patient contact are surgical stainless steel. The direct contact materials of the cited predicate devices are identical. The types of stainless steel used for these devices are well accepted in these applications, with a long history of satisfactory performance and biocompatibility.

Sterility Status: The handpieces and accessories to the SODEM HIGH SPEED SYSTEM are, like the cited predicate systems, provided non-sterile, require decontamination after use, and resterilization by the user facility.

No accessories to the SODEM HIGH SPEED SYSTEM are provided sterile, while some, but not necessarily all accessories (burrs etc) to the Zimmer Ultra Power, Midas Rex and Anspach 65K are provided sterile.

Energy Consumed - Pneumatic Power: The SODEM HIGH SPEED SYSTEM (Pneumatic Handpiece), the Zimmer Ultra Power, the Zeppelin M.D.S., Midas Rex, and Anspach 65K Systems operate using compressed air or nitrogen and controlled by foot pedal. The power of the SODEM HIGH SPEED SYSTEM is adjustable from 0-85,000 rpm. Ranges are

similar for cited predicate devices: Zimmer Ultra Power 0-70,000, Zeppelin M.D.S. 0-85,000, Midas Rex 0-72,000, and Anspach 65K System 0-65,000.

Operational Principles: The SODEM HIGH SPEED SYSTEM and all cited predicate systems use the same operational principles.